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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/931,692      | 08/14/2001  | Jim J. McGhan        | 011111              | 3354             |

7590

08/31/2004

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EXAMINER

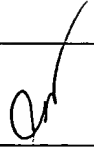
MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/931,692 | <b>Applicant(s)</b><br>MCGHAN, JIM J.  |  |
|                              | <b>Examiner</b><br>Cheryl Miller     | <b>Art Unit</b><br>3738  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 4, 6, 8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 6, 8, and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed April 26, 2004 have been fully considered but they are not persuasive. Applicant has argued that the Harish patent (US 6,506,437) does not disclose embedded particles, and Harish's composition filling the depots are not particles. The examiner disagrees. The composition 30', 34 seen in fig.9b and 9c fills a depot below the surface 20 of the article and extends outwardly therefrom, therefore 30'+34 is embedded within the article. Also, the composition 30'+34 is interpreted by the examiner to be in particulate form. Figure 9B and 9C have shown the composition 30'+34 filling one depot. The composition 30'+34 as a whole in the one depot makes up one particle, the one particle 30'+34 shown in fig.9B and 9C. Looking at a different embodiment of Harish, Harish discloses the composition 30'+34 to comprise a plurality of particles (col.6, lines 45-49), therefore, many particles exist in the composition 30'+34 seen in fig9B and 9C, some of which particles extend below and some which extend above the surface 20. In summary, Harish does indeed disclose bioabsorbable particles, and Harish has shown particles embedded within the article surface. This rejection has been maintained.

The applicant has argued that the Durgin reference (US 2002/0052653 A1) does not disclose embedded particles within the article and that open craters are not present after absorption. The examiner disagrees. The particles 32A of Durgin provide initially, an anchoring function. It is inherent that the anchors 32A must be embedded to some extent within the core 30, or else they would not be strongly attached to the implant and wouldn't be able to perform the anchoring function. And since absorption of the particles occurs, craters will inherently form

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to an extent. Also, the core 30 is disclosed to be, for instance, an open cell foam, therefore, after absorption of the particles occurs, open craters are present within the open cell foam (the craters are actually present before and after absorption, due to the structure of the core). This rejection has been maintained.

The applicant has argued that the Marotta in view of Melican rejection lacks motivation to combine and destroys the Marotta reference when combined. The examiner disagrees. The applicant's summary of the examiners rejection was inaccurate. The examiner used the Melican reference only as a teaching to show that bioglasses were absorbable (col.7, lines 3-9), therefore by combining this teaching, inherently Marotta's BIOGLASS particles were inherently if not obvious, absorbable. However, after researching the properties of bioglass, it is not clear that the bioglasses would absorb to the extent to create open craters within the core. Therefore, this rejection has been withdrawn for these reasons.

Also, it was noted that claim 11, indicated "previously presented" was seemingly amended. This claim is considered non-responsive. If the applicant intended to amend the claim, the indicator should be "currently amended" and the claim provided in a marked up fashion. If the applicant intended to write a new claim, the claim should have been renumbered to the next claim number not yet used (claim 14). Nowhere in the applicants arguments does it state that claim 11 was amended, and it has been assumed by the examiner that the amendment was unintentional. The claim will be examined as "previously presented" in the previous response mailed June 10, 2003, as indicated.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, 6, 8, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Harish et al. (USPN 6,506,437 B1, cited in previous office action). Referring to claim 2, Harish discloses a hybrid medical implant (10) comprising an elastomeric, non-bioabsorbable core portion (12, biostable polymers, col.4, lines 5-9; examples of biostable polymers listed, col.5, lines 44-49) having an outer surface (20) and a bioabsorbable portion (30', 34) affixed to the outer surface (20) of the core portion (12; see fig.9b, 9c specifically), wherein the bioabsorbable portion comprises a plurality of particles (one particle may comprise the entirety of 30'+34 in one depot, shown in fig.9c, one particle may be one drop of 34, shown in fig.9b, or one depot may comprise a plurality of particles within 30 and 34, col.6, lines 45-48) of bioabsorbable material embedded in the outer surface (20) of the core portion (12) such that an exposed portion of the particles project outwardly from the outer surface of the core portion (fig.9b, 9c; portion 30', 34 projects outward from surface 20, the portion projecting being one particle per depot, or the composition which projects outwardly from one depot containing a plurality of particles, col.6, lines 45-49) and the exposed portion of the particles and the outer surface of the core portion provide an outer surface of the hybrid medical implant and wherein the outer surface of the implant has an irregular topography (fig.9B, 9C), such that upon implantation of the implant,

the exposed portion of the plurality of particles of material project outwardly from the outer surface of the core portion (fig.9b, 9c), and after the bioabsorbable particles are absorbed, the outer surface of the core portion has a plurality of open craters there within (empty depots).

Referring to claim 4, Harish discloses a core portion (12) comprising a fluid-filled elastomeric (col.4, lines 5-9; col.5, lines 44-49) shell (the core is filled with air initially, and filled with blood, once placed in the vessel).

Referring to claim 6, Harish discloses a solid elastomeric body (12; viewing the core as a sheet, or viewing a section of the core, the cross section of the core is a solid body).

Referring to claim 8, Harish discloses an elastomeric core comprising silicone (biostable polymers, col.4, lines 5-9; silicone listed as an example of biostable polymers, col.5, lines 44-49).

Referring to claim 11, as "previously presented", Harish discloses a bioabsorbable portion (30, 34) comprising an antibiotic (col.2, lines 36-43; col.3, line 45-col.7, line 52).

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Durgin (Pub.No. US 2002/0052653 A1, cited in previous office action). Referring to claim 2, Durgin discloses a hybrid medical implant (fig.3, 12) comprising an elastomeric, non-bioabsorbable core portion (30, 30A; 0050) having an outer surface and a bioabsorbable portion (32, 32A) affixed to the outer surface of the core portion (30, 30A), wherein the bioabsorbable portion comprises a plurality of particles (32, 32A) of bioabsorbable material (0056) embedded in the outer surface of the core portion (30, 30A, fig.3, 12) such that an exposed portion of the particles project outwardly from the outer surface of the core portion (fig.3, 12) and the exposed portion of the

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particles and the outer surface of the core portion provide an outer surface of the hybrid implant and wherein the outer surface of the implant has an irregular topography (fig.3, 12), such that upon implantation of the implant, the exposed portion of the plurality of particles of material project outwardly from the outer surface of the core portion and after the bioabsorbable particles (32, 32A) are absorbed, the outer surface of the core portion has a plurality of open craters there within (0055, 0056, craters will inherently form when particles are absorbed, since particles must be embedded to some extent, otherwise, they wouldn't be attached).

Referring to claim 4, Durgin discloses a core portion (30, 30A) comprising a fluid-filled elastomeric shell (0052).

Referring to claim 6, Durgin discloses a solid elastomeric body (0051).

Referring to claim 8, Durgin discloses an elastomeric core comprising silicone (0050).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Cheryl Miller

  
BRUCE SNOW  
PRIMARY EXAMINER